

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : KUFER, et al.

Art Unit : 1642

Serial No. : 09/744,625

Examiner : Yu, M. Ph.D.

Filed : July 16, 2001

Title : HETEROMINIBODIES

Assistant Commissioner for Patents  
PO Box 1450  
Alexandria, Virginia 22313-14501

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9/15/03

RESPONSE TO OFFICE COMMUNICATION

In response to the Detailed Action mailed May 20, 2003, in connection with the above-identified application, the time to reply having been extended to August 20, 2003, by petition and fee under 37 C.F.R. §1.136(a), Applicants hereby elect the product having the following molecular structure, readable upon by Claims 1, 2, 5, 6, 7, 8, 9, 11, 19, 20, 21, 22, 33, 34, 35, 40:

HD70 V<sub>L</sub> - 14 to 25 amino acid linker - HD70 V<sub>H</sub> - arbitrary Ig hinge region - C<sub>κ</sub> or C<sub>H1</sub>

B7 - arbitrary Ig hinge region - C<sub>κ</sub> or C<sub>H1</sub>

Support for the multifunctional compound having the molecular structure shown above, with an antigen-binding region specific for a tumor antigen and a T-cell costimulatory ligand region, is found throughout the specification, in particular on page 11 at lines 14-8. Support for an antigen-binding region comprising HD70 V<sub>L</sub> and HD70 V<sub>H</sub> regions of the HD70 human anti-human EpCAM antibody is found on page 12 at lines 14-15, and on page 16, lines 3-5. Support for the T-cell costimulatory ligand region is found throughout the specification, in particular on page 11 at lines 19-31, and support for a T-cell costimulatory ligand region comprising members of the B7 family of proteins is found on page 11 at line 31 and page 12 at lines 23-25. Support for multifunctional compounds wherein polypeptides with receptor or ligand function are fused

Attorney's Docket N .: 009848 0276371

to C<sub>L</sub>(of which C<sub>K</sub> is one type) or C<sub>H1</sub> via Ig hinge regions is found throughout the specification, in particular on page 11 at lines 6-10 and on page 15 at lines 16-26. Support for choice of constant domains C<sub>K</sub> or C<sub>H1</sub> is found throughout the specification, in particular on page 6 lines 16-22 and page 15 at lines 12-14.

### CONCLUSION

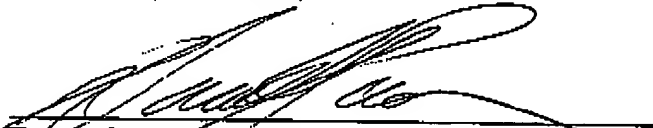
Claims 1 to 27, 33, 34, 35, 40, and 41 have been elected and are currently pending in the present application, and a request for rejoinder of Group III, claims 36 to 39, is currently pending. The molecular structure disclosed above has been elected for further examination.

A petition and fee under 37 C.F.R. §1.136(a) for extension of time to reply is submitted herewith. Please charge any additional fees, or make any credits, to Deposit Account No. 50-2212.

Respectfully submitted,

Date:

August 20, 2003

  
Donna O. Perdue, Ph.D.  
Reg. No. 51,166

Pillsbury Winthrop LLP  
11682 El Camino Real, Suite 200  
San Diego, CA 92130-2593  
Telephone: (858) 509-4093  
Facsimile: (858) 509-4010

**FAX RECEIVED**

**AUG 27 2003**

**GROUP 1600**

**OFFICIAL**

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**FAX RECEIVED****AUG 27 2003****GROUP 1600****OFFICIAL**

**FACSIMILE TRANSMISSION** Date August 26, 2003

TO: United States Patent and Trademark Office  
ATTN: Examiner Misook Yu, Ph.D. Appln No: 09/744,625  
LOCATION: Art Unit 1642 TELEPHONE #: (703) 308-2454  
USPTO  
Arlington, VA  
FAX #: (703) 305-3014 No. Pages (Including this Sheet): 9  
FROM: NAME: Donna O. Perdue C 098810 M 0278740 RETURN TO: Donna  
O.  
Perdue

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**MESSAGE PLEASE DELIVER IMMEDIATELY TO EXAMINER MISOOK YU**

**MATERIALS ENCLOSED:**

- SUPPLEMENTAL RESPONSE TO OFFICE COMMUNICATION (2 pages)
- COURTESY COPY OF PREVIOUS RESPONSE FILED AUGUST 20, 2003 (6 pages)

**CERTIFICATE OF FACSIMILE TRANSMISSION**

I hereby certify that this SUPPLEMENTAL RESPONSE TO OFFICE COMMUNICATION is being facsimile transmitted to the Patent and Trademark Office on the date shown below.

Name DONNA O. PERDUE

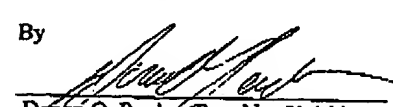
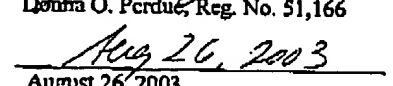
Sig. 

Date Aug 26 2003

C# 009848 / M# 0276371

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: KUFER, et al.  
 Application No.: 09/744,625  
 Filing Date: July 16, 2001  
 Art Unit 1642  
 Examiner Yu, M. Ph.D.  
 For: HETEROMINIBODIES

( CERTIFICATE OF FAX TRANSMISSION  
 ( I hereby certify under 37 C.F.R. §1.8, that this  
 ( paper and the attached papers are being  
 ( transmitted on August 26, 2003, to:  
 ( FAX NO. 703-305-3014  
 ( ATTN: Dr. MISOOK YU  
 ( By  
 (   
 ( Donna O. Perdue, Reg. No. 51,166  
 (   
 ( August 26, 2003  
 (

Assistant Commissioner for Patents  
 PO Box 1450  
 Alexandria, Virginia 22313-14501

FAX RECEIVED

AUG 27 2003

GROUP 1600

SUPPLEMENTAL RESPONSE TO OFFICE COMMUNICATION

OFFICIAL

This Supplemental Response is in response to the Detailed Action mailed May 20, 2003, in connection with the above-identified application. A Response to the Detailed Action was previously filed on August 20, 2003, the time to reply having been extended by petition and fee under 37 C.F.R. §1.136(a). Applicants request that the present Supplemental Response be entered into the record, superceding the previous Response filed August 20, 2003. A courtesy copy of the previous Response is attached after the signature page.

By this Supplemental Response, Applicants hereby elect the product having the following molecular structure, readable upon by Claims 1, 2, 5, 6, 7, 8, 9, 11, 19, 20, 21, 22, 33, 34, 35, 40:

Anti-EpCAM V<sub>L</sub> - 14-25 amino acid linker - anti-EpCAM V<sub>H</sub> - arbitrary Ig hinge region - C<sub>κ</sub> or C<sub>H1</sub>

B7 - arbitrary Ig hinge region - C<sub>κ</sub> or C<sub>H1</sub>

Support for the multifunctional compound having the molecular structure shown above, with an antigen-binding region specific for a tumor antigen and a T-cell costimulatory ligand region, is found throughout the specification, in particular on page 11 at lines 14-8. Support for an antigen-binding region comprising the anti-EpCAM V<sub>L</sub> and anti-EpCAM V<sub>H</sub> regions of anti-

70044708v2

EpCAM antibody is found on page 12 at lines 14-15, and on page 16, lines 3-5. Support for the T-cell costimulatory ligand region is found throughout the specification, in particular on page 11 at lines 19-31, and support for a T-cell costimulatory ligand region comprising members of the B7 family of proteins is found on page 11 at line 31 and page 12 at lines 23-25. Support for multifunctional compounds wherein polypeptides with receptor or ligand function are fused to  $C_L$  (of which  $C_K$  is one type) or  $C_{H1}$  via Ig hinge regions is found throughout the specification, in particular on page 11 at lines 6-10 and on page 15 at lines 16-26. Support for choice of constant domains  $C_K$  or  $C_{H1}$  is found throughout the specification, in particular on page 6 lines 16-22 and page 15 at lines 12-14.

### CONCLUSION

Claims 1 to 27, 33, 34, 35, 40, and 41 have been elected and are currently pending in the present application, and a request for rejoinder of Group III, claims 36 to 39, is currently pending. The molecular structure disclosed above has been elected for further examination.

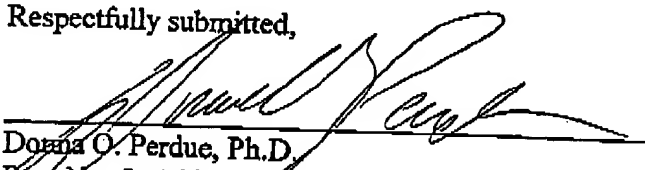
Please enter the present Supplemental Response into the record of this application. The molecular structure disclosed in the present Supplemental Response supercedes the molecular structure disclosed in the previous Response filed August 20, 2003.

A petition and fee under 37 C.F.R. §1.136(a) for extension of time to reply was submitted with the previous Response filed August 20, 2003 (see attached courtesy copy). Please charge any additional fees to Deposit Account No. 50-2212.

If the Examiner has any questions about this communication, she is encouraged to contact the Applicant's attorney at (858) 509-4093.

Respectfully submitted,

Date: August 26, 2003

  
Donna O. Perdue, Ph.D.  
Reg. No. 51,166

Pillsbury Winthrop LLP  
11682 El Camino Real, Suite 200  
San Diego, CA 92130-2593  
Telephone: (858) 509-4093  
Facsimile: (858) 509-4010

Attorney Docket No. 009848-0276371

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: KUFER, et al.  
Application No.: 09/744,625  
Filing Date: July 16, 2001  
For: HETEROMINIBODIES

**CERTIFICATE OF MAILING**

I hereby certify under 37 C.F.R. §1.8, that this paper and the attached papers are being deposited with the United States Postal Service as first class mail in an envelope addressed to:

MS: Non-Fee Amendment  
Director of Patents  
U.S. Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

*Karyn F. Massie*  
Karyn F. Massie

*August 20, 2003*  
Date

**TRANSMITTAL LETTER**

Commissioner for Patents  
U.S. Patent and Trademark Office  
Washington D.C., 20231

Sir:

Transmitted herewith for filing are the following:

1. Reply/Amendment/Letter (in duplicate);
2. Response to Office Communication (2 Pages); and
3. Return Postcard.

The Commissioner is hereby authorized to charge any fee, including any submitted herewith, if the attached check(s) is in the wrong amount or otherwise improper or missing, that may be due in connection with this and the attached papers, or with this application during its

entire pendency to or to credit any overpayment to Deposit Account 50-2212.

Respectfully submitted,

PILLSBURY WINTHROP LLP

Date:

Aug 10, 2005

By

Donna O. Perdue, Ph.D.  
Registration No. 51,166

11682 El Camino Real  
Suite 200  
San Diego, CA 92130  
Facsimile: (858) 509-4010  
Telephone: (619) 234-5000  
Direct Line: (858) 509-4093

I hereby certify that this correspondence and any paper referred to as being attached or enclosed) is being mailed via "First Class Mail" of the United States Postal Service on the date shown below in an envelope addressed to the Director of Patents, MS Non-Fee Amendment, P.O. Box 1450; Alexandria, VA 22313-1450

By: Karyn F. Massie  
Karyn F. Massie

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT APPLICATION

**Inventor(s):** Kufer, et al.

Appln. No.: 09 | 744,625

Series Code ↑	Serial No. ↑
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**Filed: July 16, 2001**

### Mail Stop Non-Fee Amendment

**Hon. Commissioner for Patents**

**PO Box 1450**

Alexandria, VA 22313-1450

Group Art Unit 1642

Examiner: Yu, M. Ph.D.

Atty. Dkt. P 009848/0276371 | C2130 US

Appln. Title: HETEROMINIBODIES

Sir,

REPLY/AMENDMENT/LETTER

**Date:** August 20, 2003

This is a reply/amendment/letter in the above-identified application and includes the herewith attachment of same date and subject which is incorporated hereinto by reference and the signature below is treated as the signature to the attachment in absence of a signature thereto.

### FEE REQUIREMENTS FOR CLAIMS AS AMENDED

1. Small Entity claim		For B & C See Required Separate Paper (Pat-255)		FEE REQUIREMENTS FOR CLAIMS AS AMENDED							
A. <input type="checkbox"/> NOT made	B. <input type="checkbox"/> Withdrawn	C. <input type="checkbox"/> made herewith	D. <input checked="" type="checkbox"/> made previously	Claims remaining after amendment	Highest number previously paid for	Present Extra	Large/Small Entity	Additional Fee	Fee Code Lg/Sm		
2. Total Effective Claims				16	**minus	41	0	x \$18/\$9 =	+ \$0	103/203	
3. Independent Claims				1	***minus	3	0	x \$84/\$42 =	+ \$0	102/202	
4. If amendment enters proper multiple dependent claim(s) into this application for first time (leave blank if this is a reissue application)..... add								+ \$280/\$140 =	+ \$0	104/204	
5. Original due Date: June 20, 2003				<input type="checkbox"/> NONE							
6. Petition is hereby made to extend the original due date to cover the date this response is filed for which the requisite fee is attached				(1 mo)	\$110/\$55 =	+ \$205				115/215	
				(2 mos)	\$410/\$205 =					116/216	
				(3 mos)	\$930/\$465 =					117/217	
				(4 mos)	\$1,450/\$725 =					118/218	
				(5 mos)	\$1,970/\$985 =					128/228	
7. Enter any previous extension fee paid since above original due date and subtract								- \$0			
8.								Extension Fee		+ \$205	
9. If Terminal Disclaimer attached, add Rule 20(d) official fee .....								+ \$110/\$55	+ \$0	148/248	
10. If IDS attached requires Official Fee under Rule 97 (c), ..... add								+ \$180	+ \$0	126	
or if Rule 97(d) Request ..... add								+ \$180		126	
11. After-Final Request Fee per rules 129(a) and 17(r) .....								+ \$750/370	+ \$0	146/246	
12. No. of additional inventions for examination per Rule 129(b) .....								x \$750/375 ea	+ \$0	149/249	
13. Request for Continued Examination (RCE) .....								+ \$750/375	+ \$0	1179/1279	
14. Petition fee for .....									+ \$0		
15.								TOTAL FEE =		\$205	
16. *If the entry in this space is less than entry in next space, the "Present Extra" result is "0".								PLEASE CHARGE OUR DEP. ACCT			
17. **If the "Highest number previously paid for" in this space is less than 20, write "20" in this space.											
18. ***If the "Highest number previously paid for" in this space is less than 3, write "3" in this space.											

**Our Deposit Account No. 50-2212**

Our Order No. 009848 0276371

CH

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08-26-03 04:25pm From-PILLSBURY WINTHROP CARMEL VLY.

858 509 4010

T-053 P.007/009 F-128

hereafter relative to this application and the resulting Official Document under Rule 20, or credit any overpayment, to our Accounting/Order Nos. shown above, for which purpose a duplicate copy of this sheet is attached.

This CHARGE STATEMENT does not authorize charge of the issue fee until/unless an issue fee transmittal sheet is filed.

Query: Is appeal deadline now? If so, file Notice of Appeals separately.

11682 El Camino Real, Suite 200

Pillsbury Winthrop LLP  
Intellectual Property Group

By Atty: Donna O. Perdue, Ph.D.

Reg. No. 51,166

San Diego, CA 92130-2092

Tel: (619) 234-5000

Atty/Sec: JRW/kfm

Sig: 

Fax: (858) 509-4010

Tel: (858) 509-4093

NOTE: File this cover sheet in duplicate with PTO receipt (PAT-103A) and attachments